105TH CONGRESS
1ST SESSION

S. 886

To reform the health care liability system and improve health care quality through the establishment of quality assurance programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 11, 1997

Mr. MCCONNELL (for himself and Mr. LIEBERMAN) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To reform the health care liability system and improve health care quality through the establishment of quality assurance programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Health Care Liability Reform and Quality Assurance Act of 1997''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—HEALTH CARE LIABILITY REFORM

Subtitle A—Liability Reform

SEC. 101. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds the following:

(1) EFFECT ON HEALTH CARE ACCESS AND COSTS.—The civil justice system of the United

States is a costly and inefficient mechanism for resolving claims of health care liability and compensating injured patients and the problems associated with the current system are having an adverse impact on the availability of, and access to, health care services and the cost of health care in the United States.

(2) EFFECT ON INTERSTATE COMMERCE.—The health care and insurance industries are industries affecting interstate commerce and the health care liability litigation systems existing throughout the United States affect interstate commerce by contributing to the high cost of health care and premiums for health care liability insurance purchased by participants in the health care system.

(3) EFFECT ON FEDERAL SPENDING.—The health care liability litigation systems existing throughout the United States have a significant effect on the amount, distribution, and use of Federal funds because of—

(A) the large number of individuals who receive health care benefits under programs operated or financed by the Federal Government;

(B) the large number of individuals who benefit because of the exclusion from Federal

taxes of the amounts spent to provide such individuals with health insurance benefits; and

(C) the large number of health care providers who provide items or services for which the Federal Government makes payments.

(b) PURPOSE.—It is the purpose of this Act to implement reasonable, comprehensive, and effective health care liability reform that is designed to—

(1) ensure that individuals with meritorious health care injury claims receive fair and adequate compensation;

(2) improve the availability of health care service in cases in which health care liability actions have been shown to be a factor in the decreased availability of services; and

(3) improve the fairness and cost-effectiveness of the current health care liability system of the United States to resolve disputes over, and provide compensation for, health care liability by reducing uncertainty and unpredictability in the amount of compensation provided to injured individuals.

SEC. 102. DEFINITIONS.

As used in this subtitle:

(1) CLAIMANT.—The term ''claimant'' means any person who commences a health care liability ac-

tion, and any person on whose behalf such an action is commenced, including the decedent in the case of an action brought through or on behalf of an estate.

(2) CLEAR AND CONVINCING EVIDENCE.—The term ''clear and convincing evidence'' means that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, except that such measure or degree of proof is more than that required under preponderance of the evidence, but less than that required for proof beyond a reasonable doubt.

(3) COLLATERAL SOURCE RULE.—The term ''collateral source rule'' means a rule, either statutorily established or established at common law, that prevents the introduction of evidence regarding collateral source benefits or that prohibits the deduction of collateral source benefits from an award of damages in a health care liability action.

(4) CONTINGENCY FEE.—The term ''contingency fee'' means any fee for professional legal services which is, in whole or in part, contingent upon the recovery of any amount of damages, whether through judgment or settlement.

(5) ECONOMIC LOSSES.—The term ''economic losses'' means objectively verifiable monetary losses incurred as a result of the provision of (or failure to provide or pay for) health care services or the use of a medical product, including past and future medical expenses, loss of past and future earnings, cost of obtaining replacement services in the home (including child care, transportation, food preparation, and household care), cost of making reasonable accommodations to a personal residence, loss of employment, and loss of business or employment opportunities. Economic losses are neither noneconomic losses nor punitive damages.

(6) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action against a health care provider, health care professional, health plan, or other defendant, including a right to legal or equitable contribution, indemnity, subrogation, third-party claims, cross claims, or counter-claims, in which the claimant alleges injury related to the provision of, payment for, or the failure to provide or pay for, health care services or medical products, regardless of the theory of liability on which the action is based. Such term does not include a product liability action, except where such an

action is brought as part of a broader health care liability action.

(7) HEALTH PLAN.—The term ''health plan'' means any person or entity which is obligated to provide or pay for health benefits under any health insurance arrangement, including any person or entity acting under a contract or arrangement to provide, arrange for, or administer any health benefit.

(8) HEALTH CARE PROFESSIONAL.—The term ''health care professional'' means any individual who provides health care services in a State and who is required by Federal or State laws or regulations to be licensed, registered or certified to provide such services or who is certified to provide health care services pursuant to a program of education, training and examination by an accredited institution, professional board, or professional organization.

(9) HEALTH CARE PROVIDER.—The term ''health care provider'' means any organization or institution that is engaged in the delivery of health care items or services in a State and that is required by Federal or State laws or regulations to be licensed, registered or certified to engage in the delivery of such items or services.

(10) HEALTH CARE SERVICES.—The term ''health care services'' means any services provided by a health care professional, health care provider, or health plan or any individual working under the supervision of a health care professional, that relate to the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of human beings.

(11) INJURY.—The term ''injury'' means any illness, disease, or other harm that is the subject of a health care liability action.

(12) MEDICAL PRODUCT.—The term ''medical product'' means a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) or a medical device as defined in section 201(h) of such Act (21 U.S.C. 321(h)), including any component or raw material used therein, but excluding health care services, as defined in paragraph (9).

(13) NONECONOMIC LOSSES.—The term ''noneconomic losses'' means losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of consortium, loss of society or companionship (other than loss of domestic serv-

ices), and other nonpecuniary losses incurred by an individual with respect to which a health care liability action is brought. Noneconomic losses are neither economic losses nor punitive damages.

(14) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not for compensatory purposes, against a health care professional, health care provider, or other defendant in a health care liability action. Punitive damages are neither economic nor noneconomic damages.

(15) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(16) STATE.—The term ''State'' means each of the several States of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

SEC. 103. APPLICABILITY.

(a) IN GENERAL.—Except as provided in subsection (c), this subtitle shall apply with respect to any health care liability action brought in any Federal or State court, except that this subtitle shall not apply to an action for damages arising from a vaccine-related injury or death to the extent that title XXI of the Public Health Service Act (42 U.S.C. 300aa-1) applies to the action.

(b) PREEMPTION.—

(1) IN GENERAL.—The provisions of this subtitle shall preempt any State law existing on, or enacted subsequent to, the date of enactment of this Act, only to the extent that such law is inconsistent with the limitations contained in such provisions and shall not preempt State law to the extent that such law—

(A) places greater restrictions on the amount of or standards for awarding noneconomic or punitive damages;

(B) places greater limitations on the awarding of attorneys fees for awards in excess of $150,000;

(C) permits a lower threshold for the periodic payment of future damages;

(D) establishes a shorter period during which a health care liability action may be initiated or a more restrictive rule with respect to the time at which the period of limitations begins to run; or

(E) implements collateral source rule reform that either permits the introduction of evidence of collateral source benefits or provides for the mandatory offset of collateral source benefits from damage awards.

(2) RULES OF CONSTRUCTION.—The provisions of this subtitle shall not be construed to preempt any State law that—

(A) permits State officials to commence health care liability actions as a representative of an individual;

(B) permits provider-based dispute resolution;

(C) places a maximum limit on the total damages in a health care liability action;

(D) places a maximum limit on the time in which a health care liability action may be initiated; or

(E) provides for defenses in addition to those contained in this Act.

(c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE OF LAW OR VENUE.—Nothing in this subtitle shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any provision of law;

(2) waive or affect any defense of sovereign immunity asserted by the United States;

(3) affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976;

(4) preempt State choice-of-law rules with respect to actions brought by a foreign nation or a citizen of a foreign nation;

(5) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss an action of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum; or

(6) supersede any provision of Federal law.

(d) FEDERAL COURT JURISDICTION NOT ESTABLISHED ON FEDERAL QUESTION GROUNDS.—Nothing in this subtitle shall be construed to establish any jurisdiction in the district courts of the United States over health care liability actions on the basis of section 1331 or 1337 of title 28, United States Code.

SEC. 104. STATUTE OF LIMITATIONS.

A health care liability action that is subject to this Act may not be initiated unless a complaint with respect to such action is filed within the 2-year period beginning on the date on which the claimant discovered or, in the exercise of reasonable care, should have discovered the injury and its cause, except that such an action relating to a claimant under legal disability may be filed within 2 years after the date on which the disability ceases. If the commencement of a health care liability action is stayed

or enjoined, the running of the statute of limitations under this section shall be suspended for the period of the stay or injunction.

SEC. 105. REFORM OF PUNITIVE DAMAGES.

(a) LIMITATION.—With respect to a health care liability action, an award for punitive damages may only be made, if otherwise permitted by applicable law, if it is proven by clear and convincing evidence that the defendant—

(1) intended to injure the claimant for a reason unrelated to the provision of health care services;

(2) understood the claimant was substantially certain to suffer unnecessary injury, and in providing or failing to provide health care services, the defendant deliberately failed to avoid such injury; or

(3) acted with a conscious, flagrant disregard of a substantial and unjustifiable risk of unnecessary injury which the defendant failed to avoid in a manner which constitutes a gross deviation from the normal standard of conduct in such circumstances.

(b) PUNITIVE DAMAGES NOT PERMITTED.—Notwithstanding the provisions of subsection (a), punitive damages may not be awarded against a defendant with respect to any health care liability action if no judgment

for compensatory damages, including nominal damages (under $500), is rendered against the defendant.

(c) PROCEDURE FOR DETERMINING PUNITIVE DAMAGES.—

(1) IN GENERAL.—In any health care liability action subject to this subtitle in which punitive damages are recoverable, the trier of fact shall determine, concurrent with all other issues presented in such action, whether such damages shall be allowed. If the trier of fact determines that such damages are allowed, a separate proceeding shall be conducted by the court to determine the amount of such damages to be awarded.

(2) SEPARATE PROCEEDING.—At a separate proceeding to determine the amount of punitive damages to be awarded under paragraph (1), the court shall consider the following:

(A) The severity of the harm caused by the conduct of the defendant.

(B) The duration of the conduct or any concealment of such conduct by the defendant.

(C) The profitability of the conduct of the defendant.

(D) The number of products sold or medical procedures rendered for compensation, as

the case may be, by the defendant of the kind causing the harm complained of by the claimant.

(E) The total deterrent effect of other damages and punishment imposed upon the defendant as a result of the misconduct, including compensatory, exemplary and punitive damage awards to individuals in situations similar to those of the claimant and the severity of any criminal or administrative penalties, or civil fines, to which the defendant has been or may be subjected.

(3) DETERMINATION.—At the conclusion of a separate proceeding under paragraph (1), the court shall determine the amount of punitive damages to be awarded with respect to the health care liability action involved and shall enter judgment for that amount. The court shall clearly state its reasons for setting the amount of such award in findings of fact and conclusions of law, demonstrating consideration of each of the factors described in paragraph (2).

(d) LIMITATION AMOUNT.—The amount of damages that may be awarded as punitive damages in any health care liability action shall not exceed 3 times the amount awarded to the claimant for the economic injury on which

such claim is based, or $250,000, whichever is greater. This subsection shall be applied by the court and shall not be disclosed to the jury.

(e) RESTRICTIONS PERMITTED.—Nothing in this Act shall be construed to imply a right to seek punitive damages where none exists under Federal or State law.

SEC. 106. PERIODIC PAYMENTS.

With respect to a health care liability action, if the award of future damages exceeds $100,000, the adjudicating body shall, at the request of either party, enter a judgment ordering that future damages be paid on a periodic basis in accordance with the guidelines contained in the Uniform Periodic Payments of Judgments Act, as promulgated by the National Conference of Commissioners on Uniform State Laws in July of 1990. The adjudicating body may waive the requirements of this section if such body determines that such a waiver is in the interests of justice.

SEC. 107. SCOPE OF LIABILITY.

(a) IN GENERAL.—With respect to punitive and noneconomic damages, the liability of each defendant in a health care liability action shall be several only and may not be joint. Such a defendant shall be liable only for the amount of punitive or noneconomic damages allocated to the defendant in direct proportion to such defendant's per-

centage of fault or responsibility for the injury suffered by the claimant.

(b) DETERMINATION OF PERCENTAGE OF LIABILITY.—With respect to punitive or noneconomic damages, the trier of fact in a health care liability action shall determine the extent of each party's fault or responsibility for injury suffered by the claimant, and shall assign a percentage of responsibility for such injury to each such party.

SEC. 108. MANDATORY OFFSETS FOR DAMAGES PAID BY A COLLATERAL SOURCE.

(a) IN GENERAL.—With respect to a health care liability action, the total amount of damages received by an individual under such action shall be reduced, in accordance with subsection (b), by any other payment that has been, or will be, made to an individual to compensate such individual for the injury that was the subject of such action.

(b) AMOUNT OF REDUCTION.—The amount by which an award of damages to an individual for an injury shall be reduced under subsection (a) shall be—

(1) the total amount of any payments (other than such award) that have been made or that will be made to such individual to pay costs of or com-

pensate such individual for the injury that was the subject of the action; minus

(2) the amount paid by such individual (or by the spouse, parent, or legal guardian of such individual) to secure the payments described in paragraph (1).

(c) DETERMINATION OF AMOUNTS FROM COLLATERAL SERVICES.—The reductions required under subsection (b) shall be determined by the court in a pretrial proceeding. At the subsequent trial—

(1) no evidence shall be admitted as to the amount of any charge, payments, or damage for which a claimant—

(A) has received payment from a collateral source or the obligation for which has been assured by a third party; or

(B) is, or with reasonable certainty, will be eligible to receive payment from a collateral source of the obligation which will, with reasonable certainty be assumed by a third party; and

(2) the jury, if any, shall be advised that—

(A) except for damages as to which the court permits the introduction of evidence, the claimant's medical expenses and lost income

have been or will be paid by a collateral source or third party; and

(B) the claimant shall receive no award for any damages that have been or will be paid by a collateral source or third party.

SEC. 109. TREATMENT OF ATTORNEYS' FEES AND OTHER COSTS.

(a) LIMITATION ON AMOUNT OF CONTINGENCY FEES.—An attorney who represents, on a contingency fee basis, a claimant in a health care liability action may not charge, demand, receive, or collect for services rendered in connection with such action in excess of the following amount recovered by judgment or settlement under such action:

(1) 33⅓ percent of the first $150,000 (or portion thereof) recovered, based on after-tax recovery, plus

(2) 25 percent of any amount in excess of $150,000 recovered, based on after-tax recovery.

(b) CALCULATION OF PERIODIC PAYMENTS.—In the event that a judgment or settlement includes periodic or future payments of damages, the amount recovered for purposes of computing the limitation on the contingency fee under subsection (a) shall be based on the cost of the annuity or trust established to make the payments. In any

case in which an annuity or trust is not established to make such payments, such amount shall be based on the present value of the payments.

SEC. 110. OBSTETRIC CASES.

With respect to a health care liability action relating to services provided during labor or the delivery of a baby, if the health care professional against whom the action is brought did not previously treat the pregnant woman for the pregnancy, the trier of fact may not find that the defendant committed malpractice and may not assess damages against the health care professional unless the malpractice is proven by clear and convincing evidence.

SEC. 111. STATE-BASED ALTERNATIVE DISPUTE RESOLUTION MECHANISMS.

(a) ESTABLISHMENT BY STATES.—Each State is encouraged to establish or maintain alternative dispute resolution mechanisms that promote the resolution of health care liability claims in a manner that—

(1) is affordable for the parties involved in the claims;

(2) provides for the timely resolution of claims; and

(3) provides the parties with convenient access to the dispute resolution process.

(b) GUIDELINES.—The Attorney General, in consultation with the Secretary and the Administrative Conference of the United States, shall develop guidelines with respect to alternative dispute resolution mechanisms that may be established by States for the resolution of health care liability claims. Such guidelines shall include procedures with respect to the following methods of alternative dispute resolution:

(1) ARBITRATION.—The use of arbitration, a nonjury adversarial dispute resolution process which may, subject to subsection (c), result in a final decision as to facts, law, liability or damages. The parties may elect binding arbitration.

(2) MEDIATION.—The use of mediation, a settlement process coordinated by a neutral third party without the ultimate rendering of a formal opinion as to factual or legal findings.

(3) EARLY NEUTRAL EVALUATION.—The use of early neutral evaluation, in which the parties make a presentation to a neutral attorney or other neutral evaluator for an assessment of the merits, to encourage settlement. If the parties do not settle as a result of assessment and proceed to trial, the neutral evaluator's opinion shall be kept confidential.

(4) EARLY OFFER AND RECOVERY MECHANISM.—The use of early offer and recovery mechanisms under which a health care provider, health care organization, or any other alleged responsible defendant may offer to compensate a claimant for his or her reasonable economic damages, including future economic damages, less amounts available from collateral sources.

(5) NO FAULT.—The use of a no-fault statute under which certain health care liability actions are barred and claimants are compensated for injuries through their health plans or through other appropriate mechanisms.

(c) FURTHER REDRESS.—

(1) IN GENERAL.—The extent to which any party may seek further redress (subsequent to a decision of an alternative dispute resolution method) concerning a health care liability claim in a Federal or State court shall be dependent upon the methods of alternative dispute resolution adopted by the State.

(2) CLAIMANT.—With respect to further redress described in paragraph (1), if the party initiating such court action is the claimant and the claimant receives a level of damages that is at least 25 per-

cent less under the decision of the court than under the State alternative dispute resolution method, such party shall bear the reasonable costs, including legal fees, incurred in the court action by the other party or parties to such action.

(3) PROVIDER OR OTHER DEFENDANT.—With respect to further redress described in paragraph (1), if the party initiating a court action is the health care professional, health care provider health plan, or other defendant in a health care liability action and the health care professional, health care provider, health plan or other defendant is found liable for a level of damages that is at least 25 percent more under the decision of the court than under the State alternative dispute resolution method, such party shall bear the reasonable costs, including legal fees, incurred in the court action by the other party or parties to such action.

(d) TECHNICAL ASSISTANCE AND EVALUATIONS.—

(1) TECHNICAL ASSISTANCE.—The Attorney General may provide States with technical assistance in establishing or maintaining alternative dispute resolution mechanisms under this section.

(2) EVALUATIONS.—The Attorney General, in consultation with the Secretary and the Administra-

tive Conference of the United States, shall monitor and evaluate the effectiveness of State alternative dispute resolution mechanisms established or maintained under this section.

SEC. 112. REQUIREMENT OF CERTIFICATE OF MERIT.

(a) REQUIRING SUBMISSION WITH COMPLAINT.—Except as provided in subsection (b) and subject to the penalties of subsection (d), no health care liability action may be brought by any individual unless, at the time the individual commences such action, the individual or the individual's attorney submits an affidavit declaring that—

(1) the individual (or the individual's attorney) has consulted and reviewed the facts of the claim with a qualified specialist (as defined in subsection (c));

(2) the individual or the individual's attorney has obtained a written report by a qualified specialist that clearly identifies the individual and that includes the specialist's determination that, based upon a review of the available medical record and other relevant material, a reasonable medical interpretation of the facts supports a finding that the claim against the defendant is meritorious and based on good cause; and

(3) on the basis of the qualified specialist's review and consultation, the individual, and if represented, the individual's attorney, have concluded that the claim is meritorious and based on good cause.

(b) EXTENSION IN CERTAIN INSTANCES.—

(1) IN GENERAL.—Subject to paragraph (2), subsection (a) shall not apply with respect to an individual who brings a health care liability action without submitting an affidavit described in such subsection if—

(A) despite good faith efforts, the individual is unable to obtain the written report before the expiration of the applicable statute of limitations;

(B) despite good faith efforts, at the time the individual commences the action, the individual has been unable to obtain medical records or other information necessary, pursuant to any applicable law, to prepare the written report requested; or

(C) the court of competent jurisdiction determines that the affidavit requirement shall be extended upon a showing of good cause.

(2) DEADLINE FOR SUBMISSION WHERE EXTENSION APPLIES.—In the case of an individual who brings an action to which paragraph (1) applies, the action shall be dismissed unless the individual submits the affidavit described in subsection (a) not later than—

(A) in the case of an action to which subparagraph (A) of paragraph (1) applies, 90 days after commencing the action; or

(B) in the case of an action to which subparagraph (B) of paragraph (1) applies, 90 days after obtaining the information described in such subparagraph or when good cause for an extension no longer exists.

(c) QUALIFIED SPECIALIST DEFINED.—

(1) IN GENERAL.—As used in subsection (a), the term ''qualified specialist'' means, with respect to a health care liability action, a health care professional who has expertise in the same or substantially similar area of practice to that involved in the action.

(2) EVIDENCE OF EXPERTISE.—For purposes of paragraph (1), evidence of required expertise may include evidence that the individual—

(A) practices (or has practiced) or teaches (or has taught) in the same or substantially similar area of health care or medicine to that involved in the action; or

(B) is otherwise qualified by experience or demonstrated competence in the relevant practice area.

(d) SANCTIONS FOR SUBMITTING FALSE AFFIDAVIT.—Upon the motion of any party or on its own initiative, the court in a health care liability action may impose a sanction on a party, the party's attorney, or both, for—

(1) any knowingly false statement made in an affidavit described in subsection (a);

(2) making any false representations in order to obtain a qualified specialist's report; or

(3) failing to have the qualified specialist's written report in his or her custody and control;

and may require that the sanctioned party reimburse the other party to the action for costs and reasonable attorney's fees.

Subtitle B—Biomaterials Access Assurance

SEC. 121. SHORT TITLE.

This subtitle may be cited as the ''Biomaterials Access Assurance Act of 1997''.

SEC. 122. FINDINGS.

Congress finds that—

(1) each year millions of citizens of the United States depend on the availability of lifesaving or life enhancing medical devices, many of which are permanently implantable within the human body;

(2) a continued supply of raw materials and component parts is necessary for the invention, development, improvement, and maintenance of the supply of the devices;

(3) most of the medical devices are made with raw materials and component parts that—

(A) are not designed or manufactured specifically for use in medical devices; and

(B) come in contact with internal human tissue;

(4) the raw materials and component parts also are used in a variety of nonmedical products;

(5) because small quantities of the raw materials and component parts are used for medical devices, sales of raw materials and component parts for medical devices constitute an extremely small portion of the overall market for the raw materials and medical devices;

(6) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), manufacturers of

medical devices are required to demonstrate that the medical devices are safe and effective, including demonstrating that the products are properly designed and have adequate warnings or instructions;

(7) notwithstanding the fact that raw materials and component parts suppliers do not design, produce, or test a final medical device, the suppliers have been the subject of actions alleging inadequate—

(A) design and testing of medical devices manufactured with materials or parts supplied by the suppliers; or

(B) warnings related to the use of such medical devices;

(8) even though suppliers of raw materials and component parts have very rarely been held liable in such actions, such suppliers have ceased supplying certain raw materials and component parts for use in medical devices because the costs associated with litigation in order to ensure a favorable judgment for the suppliers far exceeds the total potential sales revenues from sales by such suppliers to the medical device industry;

(9) unless alternate sources of supply can be found, the unavailability of raw materials and com-

ponent parts for medical devices will lead to unavailability of lifesaving and life-enhancing medical devices;

(10) because other suppliers of the raw materials and component parts in foreign nations are refusing to sell raw materials or component parts for use in manufacturing certain medical devices in the United States, the prospects for development of new sources of supply for the full range of threatened raw materials and component parts for medical devices are remote;

(11) it is unlikely that the small market for such raw materials and component parts in the United States could support the large investment needed to develop new suppliers of such raw materials and component parts;

(12) attempts to develop such new suppliers would raise the cost of medical devices;

(13) courts that have considered the duties of the suppliers of the raw materials and component parts have generally found that the suppliers do not have a duty—

(A) to evaluate the safety and efficacy of the use of a raw material or component part in a medical device; and

(B) to warn consumers concerning the safety and effectiveness of a medical device;

(14) attempts to impose the duties referred to in subparagraphs (A) and (B) of paragraph (13) on suppliers of the raw materials and component parts would cause more harm than good by driving the suppliers to cease supplying manufacturers of medical devices; and

(15) in order to safeguard the availability of a wide variety of lifesaving and life-enhancing medical devices, immediate action is needed—

(A) to clarify the permissible bases of liability for suppliers of raw materials and component parts for medical devices; and

(B) to provide expeditious procedures to dispose of unwarranted suits against the suppliers in such manner as to minimize litigation costs.

SEC. 123. DEFINITIONS.

As used in this subtitle:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) PERSONS INCLUDED.—Such term includes any person who—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.

(2) CLAIMANT.—

(A) IN GENERAL.—The term ''claimant'' means any person who brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed, who claims to have suffered harm as a result of the implant.

(B) ACTION BROUGHT ON BEHALF OF AN ESTATE.—With respect to an action brought on behalf of or through the estate of an individual into whose body, or in contact with whose blood or tissue the implant is placed, such term includes the decedent that is the subject of the action.

(C) ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT.—With respect to an action brought on behalf of or through a minor or incompetent, such term includes the parent or guardian of the minor or incompetent.

(D) EXCLUSIONS.—Such term does not include—

(i) a provider of professional health care services, in any case in which—

(I) the sale or use of an implant is incidental to the transaction; and

(II) the essence of the transaction is the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier; or

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this subtitle may be construed as a finding that silicone gel (or any other

form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not—

(aa) be disclosed to a jury in any civil action or other proceeding; and

(bb) except as necessary to establish the applicability of this subtitle, otherwise be presented in any civil action or other proceeding.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term ''component part'' means a manufactured piece of an implant.

(B) CERTAIN COMPONENTS.—Such term includes a manufactured piece of an implant that—

(i) has significant non-implant applications; and

(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

(4) HARM.—

(A) IN GENERAL.—The term ''harm'' means—

(i) any injury to or damage suffered by an individual;

(ii) any illness, disease, or death of that individual resulting from that injury or damage; and

(iii) any loss to that individual or any other individual resulting from that injury or damage.

(B) EXCLUSION.—The term does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term ''implant'' means—

(A) a medical device that is intended by the manufacturer of the device—

(i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or

(ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days; and

(B) suture materials used in implant procedures.

(6) MANUFACTURER.—The term ''manufacturer'' means any person who, with respect to an implant—

(A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 510(a)(1)) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)) of the implant; and

(B) is required—

(i) to register with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) to include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section.

(7) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) and includes any device component

of any combination product as that term is used in section 503(g) of such Act (21 U.S.C. 353(g)).

(8) RAW MATERIAL.—The term ''raw material'' means a substance or product that—

(A) has a generic use; and

(B) may be used in an application other than an implant.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(10) SELLER.—

(A) IN GENERAL.—The term ''seller'' means a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

(B) EXCLUSIONS.—The term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services, in any case in which the sale or use of an implant is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who acts in only a financial capacity with respect to the sale of an implant.

SEC. 124. GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION.

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—In any civil action covered by this subtitle, a biomaterials supplier may raise any defense set forth in section 125.

(2) PROCEDURES.—Notwithstanding any other provision of law, the Federal or State court in which a civil action covered by this subtitle is pending shall, in connection with a motion for dismissal or judgment based on a defense described in paragraph (1), use the procedures set forth in section 126.

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), notwithstanding any other provision of law, this subtitle applies to any civil action brought by a claimant, whether in a Federal or State court, against a manufacturer, seller, or biomaterials supplier, on the basis of any legal theory, for harm allegedly caused by an implant.

(2) EXCLUSION.—A civil action brought by a purchaser of a medical device for use in providing

professional services against a manufacturer, seller, or biomaterials supplier for loss or damage to an implant or for commercial loss to the purchaser—

(A) shall not be considered an action that is subject to this subtitle; and

(B) shall be governed by applicable commercial or contract law.

(c) SCOPE OF PREEMPTION.—

(1) IN GENERAL.—This subtitle supersedes any State law regarding recovery for harm caused by an implant and any rule of procedure applicable to a civil action to recover damages for such harm only to the extent that this subtitle establishes a rule of law applicable to the recovery of such damages.

(2) APPLICABILITY OF OTHER LAWS.—Any issue that arises under this subtitle and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) STATUTORY CONSTRUCTION.—Nothing in this subtitle may be construed—

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to section 1331 or 1337 of title 28, United States Code, that otherwise would not exist under applicable Federal or State law.

SEC. 125. LIABILITY OF BIOMATERIALS SUPPLIERS.

(a) IN GENERAL.—

(1) EXCLUSION FROM LIABILITY.—Except as provided in paragraph (2), a biomaterials supplier shall not be liable for harm to a claimant caused by an implant.

(2) LIABILITY.—A biomaterials supplier that—

(A) is a manufacturer may be liable for harm to a claimant described in subsection (b);

(B) is a seller may be liable for harm to a claimant described in subsection (c); and

(C) furnishes raw materials or component parts that fail to meet applicable contractual requirements or specifications may be liable for a harm to a claimant described in subsection (d).

(b) LIABILITY AS MANUFACTURER.—

(1) IN GENERAL.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.

(2) GROUNDS FOR LIABILITY.—The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier—

(A)(i) has registered with the Secretary pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and the regulations issued under such section; and

(ii) included the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C. 360(j)) and the regulations issued under such section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to—

(i) register with the Secretary under section 510 of such Act (21 U.S.C. 360), and the regulations issued under such section, but failed to do so; or

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 510(j) of such Act (21 U.S.C.

360(j)) and the regulations issued under such section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 126(c)(3)(B)(i) finds, on the basis of affidavits submitted in accordance with section 126, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) ADMINISTRATIVE PROCEDURES.—

(A) IN GENERAL.—The Secretary may issue a declaration described in paragraph (2)(B) on the motion of the Secretary or on petition by any person, after providing—

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately upon receipt of a petition filed

pursuant to this paragraph, the Secretary shall docket the petition. Not later than 180 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) APPLICABILITY OF STATUTE OF LIMITATIONS.—Any applicable statute of limitations shall toll during the period during which a claimant has filed a petition with the Secretary under this paragraph.

(c) LIABILITY AS SELLER.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant if—

(1) the biomaterials supplier—

(A) held title to the implant that allegedly caused harm to the claimant as a result of purchasing the implant after—

(i) the manufacture of the implant; and

(ii) the entrance of the implant in the stream of commerce; and

(B) subsequently resold the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the requirements described in paragraph (1), if a court

deciding a motion to dismiss in accordance with section 126(c)(3)(B)(ii) finds, on the basis of affidavits submitted in accordance with section 126, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR VIOLATING CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant, if the claimant in an action shows, by a preponderance of the evidence, that—

(1) the raw materials or component parts delivered by the biomaterials supplier either—

(A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for delivery of the product; or

(B) failed to meet any specifications that were—

(i) provided to the biomaterials supplier and not expressly repudiated by the

biomaterials supplier prior to acceptance of delivery of the raw materials or component parts;

(ii)(I) published by the biomaterials supplier;

(II) provided to the manufacturer by the biomaterials supplier; or

(III) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or

(iii) included in the submissions for purposes of premarket approval or review by the Secretary under section 510, 513, 515, or 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360, 360c, 360e, or 360j), and received clearance from the Secretary if such specifications were provided by the manufacturer to the biomaterials supplier and were not expressly repudiated by the biomaterials supplier prior to the acceptance by the manu-

facturer of delivery of the raw materials or component parts; and

(2) such conduct was an actual and proximate cause of the harm to the claimant.

SEC. 126. PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS.

(a) MOTION TO DISMISS.—In any action that is subject to this subtitle, a biomaterials supplier who is a defendant in such action may, at any time during which a motion to dismiss may be filed under an applicable law, move to dismiss the action against it on the grounds that—

(1) the defendant is a biomaterials supplier; and

(2)(A) the defendant should not, for the purposes of—

(i) section 125(b), be considered to be a manufacturer of the implant that is subject to such section; or

(ii) section 125(c), be considered to be a seller of the implant that allegedly caused harm to the claimant; or

(B)(i) the claimant has failed to establish, pursuant to section 125(d), that the supplier furnished

raw materials or component parts in violation of contractual requirements or specifications; or

(ii) the claimant has failed to comply with the procedural requirements of subsection (b).

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.—The claimant shall be required to name the manufacturer of the implant as a party to the action, unless—

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomaterials supplier is not domiciled or subject to a service of process; or

(2) an action against the manufacturer is barred by applicable law.

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed under this section:

(1) AFFIDAVITS RELATING TO LISTING AND DECLARATIONS.—

(A) IN GENERAL.—The defendant in the action may submit an affidavit demonstrating that defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)).

(B) RESPONSE TO MOTION TO DISMISS.—In response to the motion to dismiss, the claimant may submit an affidavit demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 125(b)(2)(B); or

(ii) the defendant who filed the motion to dismiss is a seller of the implant who is liable under section 125(c).

(2) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(A) IN GENERAL.—If a defendant files a motion to dismiss under paragraph (1) or (2) of subsection (a), no discovery shall be permitted in connection to the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss in accordance with the affidavits submitted by the parties in accordance with this section.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(2)(B)(i) on the grounds that the biomaterials supplier did not furnish raw materials or component parts in violation of contractual requirements or specifications, the court may permit discovery, as ordered by the court. The discovery conducted pursuant to this subparagraph shall be limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(3) AFFIDAVITS RELATING STATUS OF DEFENDANT.—

(A) IN GENERAL.—Except as provided in clauses (i) and (ii) of subparagraph (B), the court shall consider a defendant to be a biomaterials supplier who is not subject to an action for harm to a claimant caused by an implant, other than an action relating to liability for a violation of contractual requirements or specifications described in subsection (d).

(B) RESPONSES TO MOTION TO DISMISS.—The court shall grant a motion to dismiss any action that asserts liability of the defendant under subsection (b) or (c) of section 125 on

the grounds that the defendant is not a manufacturer subject to such section 125(b) or seller subject to section 125(c), unless the claimant submits a valid affidavit that demonstrates that—

(i) with respect to a motion to dismiss contending the defendant is not a manufacturer, the defendant meets the applicable requirements for liability as a manufacturer under section 125(b); or

(ii) with respect to a motion to dismiss contending that the defendant is not a seller, the defendant meets the applicable requirements for liability as a seller under section 125(c).

(4) BASIS OF RULING ON MOTION TO DISMISS.—

(A) IN GENERAL.—The court shall rule on a motion to dismiss filed under subsection (a) solely on the basis of the pleadings of the parties made pursuant to this section and any affidavits submitted by the parties pursuant to this section.

(B) MOTION FOR SUMMARY JUDGMENT.—Notwithstanding any other provision of law, if

the court determines that the pleadings and affidavits made by parties pursuant to this section raise genuine issues as concerning material facts with respect to a motion concerning contractual requirements and specifications, the court may deem the motion to dismiss to be a motion for summary judgment made pursuant to subsection (d).

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

(A) BASIS FOR ENTRY OF JUDGMENT.—A biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue as concerning any material fact for each applicable element set forth in paragraphs (1) and (2) of section 125(d).

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of material fact to exist only if the evidence submitted by claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment made pursuant to this subsection, such discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 125(d).

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 125(d) or the failure to establish the applicable elements of section 125(d) solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration pursuant to section 125(b)(3)(A) with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary has issued a final decision on the petition.

(f) MANUFACTURER CONDUCT OF PROCEEDING.—The manufacturer of an implant that is the subject of an action covered under this subtitle shall be permitted to file and conduct a proceeding on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section if the manufacturer and any other defendant in such action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of such proceeding or to conduct such proceeding.

(g) ATTORNEY FEES.—The court shall require the claimant to compensate the biomaterials supplier (or a manufacturer appearing in lieu of a supplier pursuant to subsection (f)) for attorney fees and costs, if—

(1) the claimant named or joined the biomaterials supplier; and

(2) the court found the claim against the biomaterials supplier to be without merit and frivolous.

SEC. 127. APPLICABILITY.

This subtitle shall apply to all civil actions covered under this subtitle that are commenced on or after the date of enactment of this Act, including any such action with respect to which the harm asserted in the action or the conduct that caused the harm occurred before the date of enactment of this Act.

Subtitle C—Applicability

SEC. 131. APPLICABILITY.

This title shall apply to all civil actions covered under this title that are commenced on or after the date of enactment of this Act, including any such action with respect to which the harm asserted in the action or the conduct that caused the injury occurred before the date of enactment of this Act.

TITLE II—PROTECTION OF THE HEALTH AND SAFETY OF PATIENTS

SEC. 201. ADDITIONAL RESOURCES FOR STATE HEALTH CARE QUALITY ASSURANCE AND ACCESS ACTIVITIES.

Each State shall require that not less than 50 percent of all awards of punitive damages resulting from all health care liability actions in that State, if punitive damages are otherwise permitted by applicable law, be used for activities relating to—

(1) the licensing, investigating, disciplining, and certification of health care professionals in the State; and

(2) the reduction of malpractice-related costs for health care providers volunteering to provide health care services in medically underserved areas.

SEC. 202. QUALITY ASSURANCE, PATIENT SAFETY, AND CONSUMER INFORMATION.

(a) ADVISORY PANEL.—

(1) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Administrator of the Agency for Health Care Policy and Research (hereafter referred to in this section as the ''Administrator'') shall establish an advisory panel to coordinate and evaluate, methods, procedures, and data to enhance the quality, safety, and effectiveness of health care services provided to patients.

(2) PARTICIPATION.—In establishing the advisory panel under paragraph (1), the Administrator shall ensure that members of the panel include representatives of public and private sector entities having expertise in quality assurance, risk assessment, risk management, patient safety, and patient satisfaction.

(3) OBJECTIVES.—In carrying out the duties described in this section, the Administrator, acting through the advisory panel established under paragraph (1), shall conduct a survey of public and private entities involved in quality assurance, risk assessment, patient safety, patient satisfaction, and practitioner licensing. Such survey shall include the gathering of data with respect to—

(A) performance measures of quality for health care providers and health plans;

(B) developments in survey methodology, sampling, and audit methods;

(C) methods of medical practice and patterns, and patient outcomes; and

(D) methods of disseminating information concerning successful health care quality improvement programs, risk management and patient safety programs, practice guidelines, patient satisfaction, and practitioner licensing.

(b) GUIDELINES.—Not later than 2 years after the date of enactment of this Act, the Administrator shall, in accordance with chapter 5 of title 5, United States Code, establish health care quality assurance, patient safety and consumer information guidelines. Such guidelines shall be modified periodically when determined appropriate by the Administrator. Such guidelines shall be advisory in nature and not binding.

(c) REPORTS.—

(1) INITIAL REPORT.—Not later than 6 months after the date of enactment of this Act, the Administrator shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the

Committee on Commerce of the House of Representatives, a report that contains—

(A) data concerning the availability of information relating to risk management, quality assessment, patient safety, and patient satisfaction;

(B) an estimation of the degree of consensus concerning the accuracy and content of the information available under subparagraph (A);

(C) a summary of the best practices used in the public and private sectors for disseminating information to consumers; and

(D) an evaluation of the National Practitioner Data Bank (as established under the Health Quality Improvement Act of 1986), for reliability and validity of the data and the effectiveness of the Data Bank in assisting hospitals and medical groups in overseeing the quality of practitioners.

(2) INTERIM REPORT.—Not later than 1 year after the date of enactment of this Act, the Administrator shall prepare and submit to the Committees referred to in paragraph (1) a report, based on the results of the advisory panel survey conducted under subsection (a)(3), concerning—

(A) the consensus of indicators of patient safety and risk;

(B) an assessment of the consumer perspective on health care quality that includes an examination of—

(i) the information most often requested by consumers;

(ii) the types of technical quality information that consumers find compelling;

(iii) the amount of information that consumers consider to be sufficient and the amount of such information considered overwhelming; and

(iv) the manner in which such information should be presented;

and recommendations for increasing the awareness of consumers concerning such information;

(C) proposed methods, building on existing data gathering and dissemination systems, for ensuring that such data is available and accessible to consumers, employers, hospitals, and patients;

(D) the existence of legal, regulatory, and practical obstacles to making such data available and accessible to consumers;

(E) privacy or proprietary issues involving the dissemination of such data;

(F) an assessment of the appropriateness of collecting such data at the Federal or State level;

(G) an evaluation of the value of permitting consumers to have access to information contained in the National Practitioner Data Bank and recommendations to improve the reliability and validity of the information; and

(H) the reliability and validity of data collected by the State medical boards and recommendations for developing investigation protocols.

(3) ANNUAL REPORT.—Not later than 1 year after the date of the submission of the report under paragraph (2), and each year thereafter, the Administrator shall prepare and submit to the Committees referred to in paragraph (1) a report concerning the progress of the advisory panel in the development of a consensus with respect to the findings of the panel and in the development and modification of the guidelines required under subsection (b).

(4) TERMINATION.—The advisory panel shall terminate on the date that is 3 years after the date of enactment of this Act.

TITLE III—SEVERABILITY

SEC. 301. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

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